Reusing routinely collected clinical data for medical device surveillance

Graeme Hickey*, Joel Dunning, Iain Buchan, Ben Bridgewater

*Department of Epidemiology & Population Health, Institute of Global Health, University of Liverpool, graeme.hickey@liverpool.ac.uk

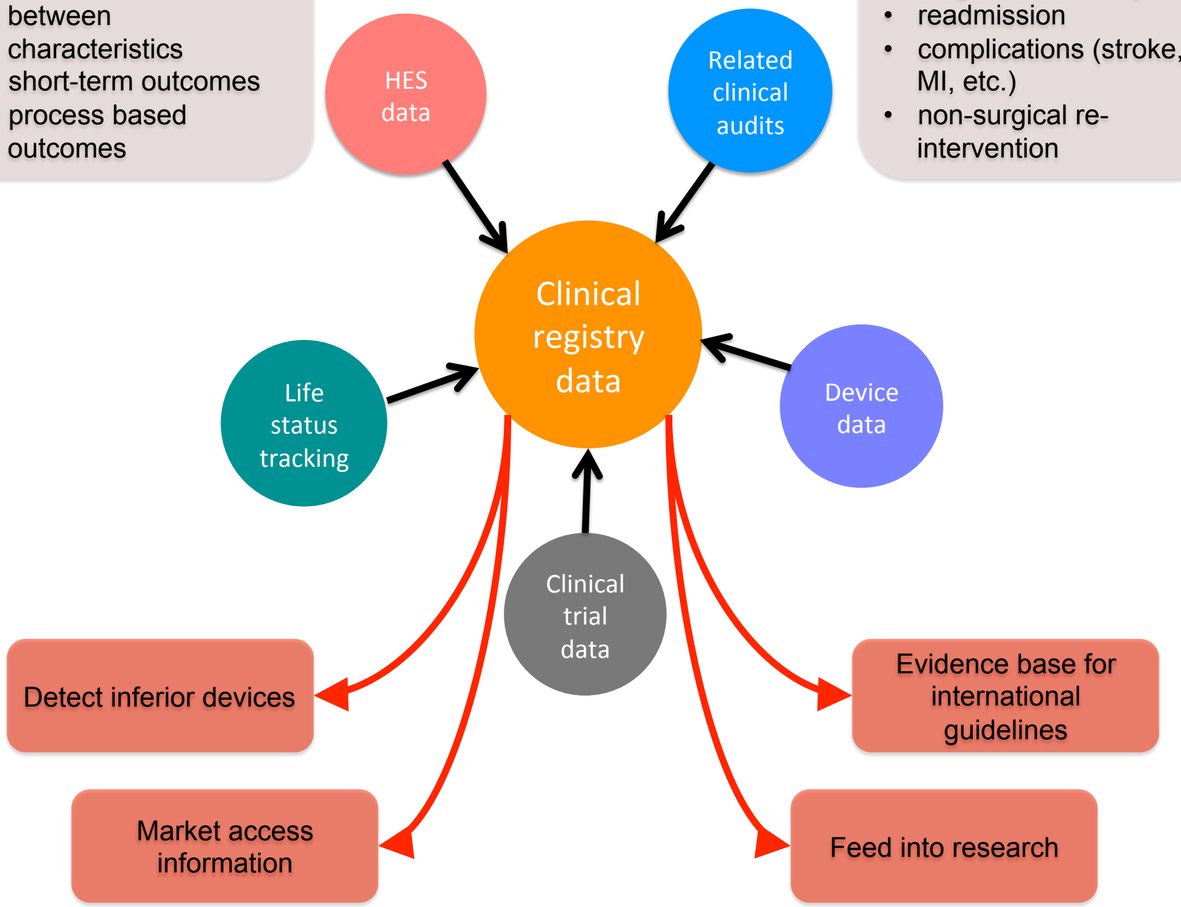
BACKGROUND

Following the serious failings in healthcare surrounding Poly Implant Prothèse breast implants, there is increased focus on the surveillance of medical devices, in particular surgical implants. This clinical epidemiology has historically been impeded by a lack of data on the procedures performed in insufficient linkage of those data to subsequent outcomes.

Registry can be used to explore:
- clinical differences between characteristics
- short-term outcomes
- process based outcomes

Temporal and spatial data can be used to explore equity of treatment access

With record linkage, can monitor:
- long-term mortality
- readmission
- complications (stroke, MI, etc.)
- non-surgical re-intervention



APPLICATION TO PROSTHETIC HEART VALVES

The National Adult Cardiac Surgery Audit has collected data on all cardiac operations since the 1990s, including free-text information on prosthetic heart valve implants. Through development of algorithms to clean the registry and classify prosthesis models, and combine with clinical data to assess/monitor performance and trends. The graphs below show a simplified illustrated clinical example for 2 valve models – a mechanical and biological – from a working dataset of >95,000 aortic valve replacements and 100 model classifications.